DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 8 2000

Ms. Nancy Y. Street
Director of Process Engineering
Platinum Services, Incorporated
115 Boise Street
DeQuincy, Los Angles 70633

Re: K001175
Trade Name: Seragard Vascular Access Patch
Regulatory Class: II
Product Code: FMI
Dated: July 27, 2000
Received: August 1, 2000

Dear Ms. Street:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Susan Runner

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications

The SeraGard™ Vascular Access Patch (VAP) is a sterile wound isolation device for clinical blood withdrawal or intravenous injection procedures. It is a self-adhesive pad intended to contain blood during a blood drawing procedure or intravenous injection. It is an extension of the concept for blood containment and wound isolation demonstrated in the Targett™ Injection Patch (K952606). The SeraGard™ VAP is placed over the site of the injection (held in place by adhesive backing), and the needle penetrates the center of the device before entering the skin. Following the procedure, the device is discarded after hemostasis; it is not intended to act as a dressing. Its mode of use is shown schematically in Figure A.

The SeraGard™ VAP is indicated for use in blood drawing or intravenous injection procedures to contain blood and isolate the wound. It is intended to minimize the risk of contamination of healthcare workers' contacting the patient's blood by isolating the wound site and absorbing the blood until hemostasis has occurred. It is also intended to isolate the patient and the healthcare worker from the wound site, acting as a barrier device from other environmental contaminants.

The SeraGard™ VAP is indicated for a maximum in-site duration of 48 hours.

Patricia Cicerale

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K001175